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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YU, MELANIE J

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,805	Applicant(s) NAKAJIMA ET AL.	
	Examiner MELANIE YU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-25 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-12, 15-19 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/25, 5/23, 9/24</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 23 May 2008 has been entered.
2. Applicant's election of a mite antigen protein in the reply filed on 24 September 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13, 14, 20 and 21 have been withdrawn as being drawn to a non-elected invention.

Information Disclosure Statement

3. The references indicated with a strike-through in information disclosure statements filed 25 April 2008 and 23 May 2008 have not been considered because the references are not properly formatted for non-patent literature references. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. Applicant's amendment recites that the electrolyte thin film is formed by using a solution that does not include a separate inorganic salt, which is not provided for in the instant specification. It is noted that examples 1-4 in the instant specification do not describe the solution including a separate inorganic salt, but also does not provide teaching the exclusion of a separate inorganic salt from the solution. Therefore this limitation is new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 4-9, 16, 23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Laguitton (US 6,689,478).

Laguitton teaches an immobilization support comprising: on the surface of the support an electrolyte thin film (col. 3, lines 20-25) as an adsorbing film for binding material (col. 3, lines 29-34), wherein the electrolyte thin film comprises alternating layers of a polyanionic thin film and a polycationic thin film (col. 4, lines 50-66) so that the uppermost layer is a polycationic thin film (col. 5, lines 27-28). Laguitton does not specifically teach the limitations of: the electrolyte thin film formed by using a solution that does not include a separate inorganic salt, at least one layer formed by using a

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solution comprising a salt of a water-soluble polymer or the thin film formed by using a solution consisting essentially of water and a water-soluble polymer or a salt of a water-soluble polymer. However such a limitation is drawn to a method of making the support and does not provide any structural features for the support. Since the rejected claim is drawn to a product the method of making the products need not be the same, but the methods must result in the same final product. The immobilization support of Laguitton teaches the recited structural features of the claim of layers of polycationic and polyanionic thin films on a support surface, therefore the final product of the prior art and the recited claims are the same.

Regarding claims 5-8, Laguitton teaches the immobilization support having a binding material that binds to a substance to be detected immobilized to the support (col. 6, lines 1-37) wherein the binding material is a biologically derived material of a protein or nucleic acid (col. 6, lines 19-37).

With respect to claim 9, Laguitton teaches the electrolyte thin film comprising a polyallylamine thin film (col. 5, lines 4-5 and 17) and a polyacrylic acid thin film (col. 5, lines 4-5), which are polycationic and polyanionic, respectively, wherein the polycationic polymer, which is polyallylamine is the uppermost layer (col. 5, lines 27-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 10-12, 15, 17-19, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laguitton (US 6,689,478), as applied to claims 4 and 16, in view of Tanga et al. (WO 02/095408). Since Tanga et al. is published in Japanese, the English equivalent document US 2004/0241883 is referred to herein for citations. The English equivalent is a 371 filing of WO 02/095408 and documents have the same abstract and figures, so the documents are expected to contain the same subject matter. Furthermore, a direct translation of WO 02/095408 will be provided upon request of applicant.

Laguitton teaches a protein immobilized to an immobilization support, but fail to teach the protein being a mite antigen.

Tanga et al. teach a mite antigen immobilized to a substrate (allergen immobilized to support, par. 24; allergen is a mite antigen, 170; Fig. 2), in order to provide specific analysis of a sample for an allergy.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the protein immobilized to the substrate of Laguitton, a mite antigen as taught by Tanga et al. because Laguitton is generic with

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respect to the proteins that can be immobilized on the support and one would be motivated to use the appropriate protein for detection of a desired analyte.

With respect to claims 11, 12, 18 and 19, Laguitton teaches an electrolyte film having 5 layers of alternating polycationic and polyanionic films on a substrate (col. 4, line 57-col. 5, line 3) or 18 layers (9 bilayers are fixed on a substrate, col. 6, lines 40-48; bilayers include a polycationic layer attached to an oppositely charged polyanionic layer, col. 4, lines 47-66), wherein the polycationic and polyanionic films are polyallylamine and polyacrylic acid, respectively (col. 5, lines 4-20). Although Laguitton does not specifically teach 20 layers of polycationic and polyanionic layers on a substrate, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation” Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. at 458, 105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claim 12 are for any particular purpose or solve any stated problem, and the prior art teaches that the number of layers may be varied in order to provide varying degrees of binding. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable

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ranges of the methods disclosed by the prior art by normal optimization procedures know in the electrolyte film art.

With respect to claims 15, 22 and 24, Laguitton teaches the immobilization support, but fail to teach a kit comprising the support.

Tanga et al. teach a kit comprising a mite allergy diagnosis substrate (par. 10 and 147-148), in order to test for allergies.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the support of Laguitton, in a kit as taught by Tanga et al., in order to provide an economical and convenient storage of the support.

Response to Arguments

Applicant's arguments regarding claims 4-9, 16, 23 and 25, filed 23 May 2008 have been fully considered but they are not persuasive. Applicant argues that Laguitton teaches a charged film deposited in a solution of polyelectrolyte mixed with inorganic salt, and therefore fail to teach depositing layers in the absence of inorganic salt. Applicant's argument is not persuasive because such a limitation is drawn to a method of making the support and does not provide any structural features for the support. Since the rejected claim is drawn to a product the method of making the products need not be the same, but the methods must result in the same final product. The immobilization support of Laguitton teaches the recited structural features of the claim of layers of polycationic and polyanionic thin films on a support surface, therefore the final product of the prior art and the recited claims are the same.

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7. Applicant further argues that Laguitton does not disclose a substrate having thin films comprising alternating layers of a polyallylamine thin film and polyacrylic acid thin film so that the upper most layer is a polyallylamine thin film. Applicant's argument is not persuasive because Laguitton teaches that polycationic and polyanionic thin films are layered with a polycationic film as the uppermost layer. Laguitton also discloses electrolyte films being selected from a group of films comprising polyallylamine and polyacrylic acid, which are polycationic and polyanionic, respectively. Therefore Laguitton teaches alternating layers of polyallylamine thin film and polyacrylic acid thin film.

8. Applicant's arguments with respect to claims 10-12, 15, 17-19, 22 and 24 have been considered but are moot in view of the new ground(s) of rejection. A new ground(s) of rejection is made in view of applicant's addition of new claims requiring the new limitations of a protein to be a mite antigen and a kit comprising the support.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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